FDA Commissioner Jane Henney Food and Drug Administration 5600 Fishers Lane, Room 14-71 Rockville, MD 20857

RE: Docket 99P-0033/CP 1

Dear Commissioner Henney:

I'm enclosing for your review a copy of an article sent to me by the Humane Farming Association (HFA).

It seems unconscionable to me that Federal agencies do not even require State health officials to report Transmissible Spongiform Encephalopathies (TSEs).

Please require the FDA to act immediately and responsibly on HFA's petition. I am becoming ever more concerned and convinced that the FDA and the USDA are not doing nearly enough to educate and protect the public, whereas these agencies are doing more than enough to protect the meat and dairy industries.

I'd like to also request that you take time to read the book by Gail Eisnitz entitled Slaughterhouse -- it's a book that could, and perhaps should, change your life.

Thank you very much for your courtesy in replying.

Sincerely.

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Enclosure

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HFA Files Legal Petitions to Combat MAD COW Disease in the United States

ou may have seen in the nation's newspapers several weeks ago a chilling report that hinted at the magnitude of what may be the world's next great epidemic.

A panel of Food and Drug Administration (FDA) scientists have asked our government to prohibit blood donations from people who have lived in England in the last twenty years. Their concern is that these people may have eaten meat infected with mad cow disease and could be at risk for getting and spreading the disease here in the U.S.

Don't expect the FDA, however, to voluntarily adopt this recommendation from its own scientific advisors. For the FDA is already ignoring even more compelling scientific warnings about mad cow disease, in particular, the dangers of feeding dead animals to farm animals.

It is because of this inaction that HFA has filed two formal legal petitions demanding that the federal government act immediately to monitor and prevent mad cow type diseases in the U.S. Joining with HFA in this effort are the Center for Food Safety, the Center for Media & Democracy, and several families of CJD victims.

The Silent Killer

Transmissible Spongiform Encephalopathies (TSEs) are killing people, deer, elk, and sheep in the U.S. TSEs are a mysterious class of diseases that are called by different names in different species.

Some identified types of TSEs are Creutzfeldt-Jakob Disease (CJD) and new variant Creutzfeldt-Jakob Disease (nvCJD) which is a human disease apparently caused by the same agent which causes bovine spongiform encephalopathy (BSE) or mad cow disease.

HFA's demand for immediate government action is given added urgency by the case of a thirty-year old Utah man who is now terminally ill with CJD, a mad

Douglas McEwen may have contracted CJD by eating or handling deer or elk infected with mad deer disease. Additionally, there is concern that, as a frequent blood donor, he may have inadvertently passed on contaminated blood to others.

Commenting to the news media on the petitions, HFA's National Director Bradley Miller stated, "TSEs represent a potentially devastating threat to both human and animal health. Given what we know now, it is unconscionable that our government is still allowing the feeding of blood and other animal

by-products to farm animals."

The common characteristic of TSE diseases is that they are invariably fatal. They can be transmitted to humans through exposure

humans through exposure to contaminated human growth hormone, corneal transplants, the use of dura mater in transplants, the use of infected probes, and possibly through blood.

A major route of transmission occurs through ingestion of the

"It is unconscionable that our government is still allowing the feeding of blood and other animal byproducts to farm animals."

infectious agent, such as eating infected meat. The agent does not trigger an immune response. The doomed animal or human appears to be in perfectly normal health for a significant portion of their lifetime.

Later, the disease emerges as holes and amyloid plaque material spreading in the brain, causing symptoms of dementia (which routinely appears to be Alzheimer's Disease), physical failure, and death.

Before a human or animal exhibits symptoms there is no way to test for the disease even though the human or animal is infected and contagious.

The common characteristic of TSE diseases is that they are invariably fatal.

Prior to the appearance of nvCJD, the

best known occurrence of a TSE in humans was the disease kuru, a TSE that appeared in the Fore tribe in New Guinea in the early 20th century. This disease was spread by cannibalistic rituals, including not only the consumption of brain but exposure of brain matter to mucous membranes and cuts in the skin.

Just as cannibalistic rituals produced the TSE kuru in humans, forcing farm animals to become "cannibals"

creates the same problems.

British mad cow disease (BSE) appeared in the mid-1980s. It quickly spread from just a few animals to infect hundreds of thousands.

By 1988, this disease was linked to feeding rendered animal by-products to livestock. British cattle were consuming the remains of sheep, cattle, and other animals deemed unfit for human consumption.

Despite the British outbreak, the dangerous practice of feeding rendered meat and bonemeal to livestock has been widely practiced in the U.S., where no meaningful restrictions were even attempted until August 1997.

Today, the U.S. still allows practices that should be banned, such as feeding pigs to pigs, pigs to cattle, and

SUMMARY OF HFA'S PETITION TO THE FOOD AND DRUG ADMINISTRATION (FDA)

In its first petition, HFA demands that:

- Blood and blood products from all mammals, including pigs and cows, must be prohibited for use in animal feed and pet foods.
- Gelatin and gelatin by-products must not be used in animal feed, as gelatin might carry infectious agents.
- Porcine materials must not be used in animal feed because U.S. pigs are known to have exhibited symptoms of central nervous system disease suspected as being TSE and have proven susceptible to TSE in laboratory tests.
- TSE-positive material absolutely must not be fed to any animals or be used in cosmetics, fertilizer or other products.

cattle blood products to calves. These practices are allowed despite suggestive evidence that TSE disease may already infect pigs, cattle, and squirrels and despite the existence of proven TSEs in sheep, deer, elk, and

To date, 33 human beings have died from new variant Creutzfeldt-Jakob Disease (nvCJD), apparently contracted from cattle infected with BSE. How many more will die is uncertain.

Due to the long incubation period, it will be many years before the extent of the disease and deaths are determined. Estimates now range from dozens to hundreds of thousands of eventual deaths from nvCJD in

CJD also exists in the U.S., but it is unclear at what level. Most CJD here is considered "sporadic" with an unknown cause. However, the U.S. has a large population of persons with various dementia diseases, the most often diagnosed being Alzheimer's (four million cases). And studies of people in the U.S. who have died of dementia suggest much higher levels of CJD than commonly suspected.

Unlike virtually all other diseases, including AIDS, where the infectious agent can be detected in the early stages of the incubation process, doctors are unable to determine if a person is infected with TSE until right before symptoms occur.

Currently, federal agencies do not even require state health officials to report TSE cases.

SUMMARY OF HFA'S PETITION TO THE CENTERS FOR DISEASE CONTROL (CDC)

HFA's second petition demands that the CDC:

- Initiate a significant epidemiological investigation to determine the incidence of transmissible spongiform encephalopathies among the human population of the U.S.
- Develop an ongoing national monitoring and registry program utilizing autopsy examinations to determine any changes in the incidence of CJDlike diseases among the human population of the U.S.
 - Direct all state medical officers to engage in a reporting process, similar to the reporting requirements of other infectious and transmissible diseases, to the CDC for the purpose of establishing a national cumulative database and reporting system.

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